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BI, Lilly announces results of new post-hoc analysis of data from the EMPA-REG OUTCOME trial

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Boehringer Ingelheim and Eli Lilly and Company have announced results of a new post-hoc analysis of data from the EMPA-REG OUTCOME trial. These results indicated that the effect of empagliflozin on reducing cardiovascular and renal risk was consistent between a sub-group of adults with type 2 diabetes and established cardiovascular disease, who also have a form of chronic kidney disease without overt proteinuria (high levels of protein in the urine), and all others in the trial.1 The results were shared as an oral presentation at the 79th American Diabetes Association (ADA) Scientific Sessions on 10 June in San Francisco, California, US.

“We are pleased to share new research data from the landmark EMPA-REG OUTCOME® trial, examining the effects of empagliflozin in adults with type 2 diabetes who have an increasingly common, yet infrequently studied, form of chronic kidney disease,” said Waheed Jamal, MD, Corporate Vice President and Head of CardioMetabolic Medicine, Boehringer Ingelheim. “The results support the need for additional studies aimed at addressing important unmet medical needs for people with various forms of kidney disease. To that end, we have initiated a large outcomes trial, EMPA-KIDNEY, to investigate the effects of empagliflozin on cardiovascular death and the progression of kidney disease in a broad population of adults with chronic kidney disease.”

Globally, more than 500 million people are affected by chronic kidney disease, up to 40 per cent of whom have diabetes.2,3,4 Chronic kidney disease is typically accompanied by the presence of varying amounts of protein in the urine, known as proteinuria.5 The majority of people with chronic kidney disease, however, have normal to moderately-increased urinary protein levels, rather than overt proteinuria.5 Kidney disease without overt proteinuria is becoming more common yet is rarely studied in clinical trials, despite the known increased risk for adverse outcomes.5

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consistent between people in the EMPA-REG OUTCOME trial who had chronic kidney disease without overt proteinuria and all others in the trial.1 Outcomes examined included cardiovascular death, hospitalisation for heart failure, new or worsening kidney disease, and the combination of cardiovascular death or hospitalisation for heart failure, as well as safety outcomes of interest.1

Furthermore, results from a separate post-hoc analysis recently presented at the ISN World Congress of Nephrology 2019, indicated that the effect of empagliflozin on the cardiorenal outcome*, was consistent between people in the EMPA-REG OUTCOME trial who had proteinuric kidney disease and all others in the trial. Together, these post-hoc analyses suggest that the effect of empagliflozin on cardiorenal outcomes is consistent regardless of whether patients have proteinuric kidney disease or not.

“These new findings are just one part of a broad and comprehensive clinical development programme that explores how empagliflozin can improve patient health outcomes and fill therapeutic gaps to serve as a broad cardiometabolic treatment option,” said Sherry Martin, MD, Vice President, Medical Affairs, Lilly. “We look forward to gathering additional information through results from EMPA-KIDNEY, which will examine the potential for empagliflozin to improve outcomes for people with chronic kidney disease, including those with and without proteinuria.”

EMPA-KIDNEY will enrol approximately 5,000 adults with chronic kidney disease both with and without diabetes as well as with and without proteinuria worldwide.6

*Defined as end-stage kidney disease (initiation of maintenance renal replacement therapy or sustained eGFR <15 ml/min/1.73m2), sustained doubling or creatinine, or renal/cardiovascular death.

The study of heart and kidney protection with empagliflozin6 EMPA-KIDNEY (NCT03594110) is a multinational randomised, double-blind, placebo-controlled clinical trial, designed to evaluate the effect of empagliflozin on clinically relevant outcomes: kidney disease progression and cardiovascular mortality risk. The primary outcome is defined as time to a first event of either a cardiovascular death or kidney disease progression, defined as end-stage kidney disease (the need for kidney replacement therapy such as, dialysis or kidney transplantation), a sustained decline in eGFR to <10mL/min/1.73m2, renal death or a sustained decline of ?40 percent in eGFR from randomisation. EMPA-KIDNEY includes people with established chronic kidney disease both with and without diabetes, receiving either empagliflozin 10 mg or placebo, on top of current standard of care.

EMPA-KIDNEY is an academic collaboration, independently conducted, analysed and reported by the Medical Research Council Population Health Research Unit at the University of Oxford (MRC PHRU), which is based in the Clinical Trial Service Unit and Epidemiological Studies Unit (CTSU). Boehringer Ingelheim and Lilly are providing the funding for the study as part of their commitment to advancing treatments and pioneering research to address the public health challenges of cardiovascular, metabolic and kidney diseases beyond type 2 diabetes.

Chronic kidney disease is defined as a progressive decline of kidney function over time. About two thirds of chronic kidney disease cases are attributable to metabolic conditions such as diabetes (known as diabetic kidney disease), obesity and hypertension.[7,8,9]

Notably, chronic kidney disease is associated with increased morbidity and mortality. The majority of deaths among people with chronic kidney disease occur as a result of cardiovascular complications, often before reaching end-stage kidney disease.[10,11,12]Once end-stage kidney disease is reached, affected individuals have to undergo kidney replacement treatments, such as chronic dialysis or kidney transplantation.[13] Chronic kidney disease is highly prevalent in various parts of the world, affecting more than 10 percent of the population.[14] Since there is currently no approved treatment available to specifically reduce kidney disease progression and cardiovascular death, the overarching unmet medical need for new treatment options in people with chronic kidney disease is evident.

Please click on the following link for ‘Notes to Editors’ and ‘References’: http://www.boehringer-ingelheim.com/press-release/type-2-diabetes-cardiorenal-post-hoc-analysis